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EXAMINER	
SASAN, ARADHANA	
ART UNIT	PAPER NUMBER
1615	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/802,240	CAVASSINI ET AL.	
	Examiner	Art Unit	
	ARADHANA SASAN	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 October 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7,9-18,20-39,41,43-49,52 and 55-59* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,9-18,20-39,41,43-49,52 and 55-59* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/20/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application

1. The remarks and amendments filed on 10/20/09 are acknowledged.

2. Claims 8, 19, 40, 42, 50-51 and 53-54 were cancelled.

3. Claims 1-7, 9-18, 20-39, 41, 43-49, 52, and 55-59 were amended and are included in the prosecution.

Information Disclosure Statement

4. The information disclosure statement (IDS) filed on 10/20/09 is acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97 and 1.98. Accordingly, the examiner is considering the information disclosure statement. See attached copy of PTO-1449.

New Rejection – necessitated by amendment

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1, 7 and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. Claim 1 recites “said core **mainly consisting of** choline chloride” in line 9 and “the second layer **mainly consisting of** carnauba wax” in line 17. Since the terms “consisting of” are considered closed language, it is unclear how Applicant intends "mainly consisting of" to be closed language.

8. Claim 7 recites "wherein the core further comprises a … flow modifier". Claim 7 is dependent on claim 1 which has closed language regarding the core. It is unclear how a flow modifier can be further included in the core if the core consists mainly of choline chloride.

9. Claim 9 also recites a "flow modifier" and it is unclear how a flow modifier can be further included in the core if the core consists mainly of choline chloride.

MAINTAINED REJECTIONS:

The following is a list of maintained rejections:

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. Claims 1-7, 22-39, 46-49, 52 and 55-59 **remain** rejected under 35 U.S.C. 103(a) as being unpatentable over Iijima et al. (US 4,948,589) in view of Spires (US 4,394,377) and further in view of Ito et al. (US 6,299,912 B1).

The claimed invention is a composition of matter for feeding to a ruminant. The composition is a pellet comprising particles compressed together via pelletization. Each of the particles contains choline chloride to be administered in a rumen-protected and post-ruminally effective form. Each particle comprises a core which contains choline chloride and a protective coating surrounding the core which provides effective protection of the choline chloride from ruminal activity while allowing effective release of

the choline chloride into the post-rumen portion of the digestive tract of the ruminant. The core mainly consists of choline chloride in the form of a dry, crystalline powder and, in combination, the protective coating surrounding the core comprises an outer, continuous layer mainly consisting of carnauba wax and an inner, continuous layer consisting of a hydrophobic substance selected from the group consisting of vegetable oils, hydrogenated vegetable oils, stearic acid and mixtures thereof. The inner layer provides effective protection of the choline chloride from moisture.

Iijima teaches a granular composition containing choline for a ruminant. The granular composition is "capable of reaching an abomasum and downstream thereof substantially in the form of granules, without easily dissolved or decomposed in the rumen" (Col. 2, lines 3-9). Choline chloride is a preferable choline derivative (Col. 2, lines 45-46). Hydrophobic agents such as hydrogenated palm oil, hydrogenated soybean oil, stearic acid, and carnauba wax are disclosed as binders and overcoating agents for the granules (Col. 3, lines 34-40 and lines 50-56). It is also disclosed that the granular composition may contain "any ingredients conventionally used in the animal feed, especially for a ruminant" (Col. 4, lines 9-15). The choline chloride is powdered since the particle size is disclosed. "Cholines having an average particle size of 100μm or less … and a maximum particle size of 150μm or less … are granulated with excipients and hydrophobic binders" (Col. 4, lines 18-27). The particle size of choline chloride is achieved by grinding in an appropriate grinder (Col. 4, lines 42-46). Granulation methods such as fluidized granulation and agitation granulation are disclosed (Col. 5, lines 44-53). "… When the agitation granulation is used, relatively

spherical or round granulated particles, which are suitable for subsequent coating, can be advantageously obtained … the fluidizable binder is migrated to the surface of the granules during the granulation to form a surface layer. As a result, the choline and other powder to be protected is relatively located in the inside portion of the granules" (Col. 5, lines 54-64). The resultant granules have a particle size of 0.5 to 2.5mm (Col. 6, lines 49-51). The choline granules "are overcoated with a thin film by adding 20 to 40 parts, preferably 20 to 30 parts by weight, of a molten mixture, … of a hydrophobic overcoating agent and a solubility modifier …" (Col. 6, line 67 to Col. 7, line 6). "When the dissolution test of Example 1 was carried out with respect to the inner granules of Example 1 in which the overcoating was not applied, the dissolution rate in the rumen solution was 99%. As a result, the choline chloride was substantially completely dissolved in a rumen corresponding solution. Thus, when the coating is not applied, the desired resistance is not obtained" (Col. 9, lines 44-52).

Iijima does not expressly teach the overcoating of the choline chloride comprising an outer layer of carnauba wax and an inner layer of a hydrophobic substance or pelletization of the choline chloride composition.

Spires teaches a composition that comprises choline in the form of pellets and pelleted feeds (Col. 13, lines 10-25). The finished feed product comprising choline may be mixed with cattle feed components that are particularly suited for ruminants (Col. 14, lines 34-49).

Ito teaches a preparation for administration to animals (including cattle) and a feed containing the preparation (Col. 1, lines 14-18 and lines 48-49). Ito teaches that

pelletization of feed materials involves heating or pressurization, active ingredients such as L-ascorbic acid 2-phosphoric ester salt are degraded under these conditions, and that "the depletion efficiency" of the active ingredient "must be restrained to the minimum limit" (Col. 2, lines 25-59). The preparation of the active ingredient is coated with a digestible and a non-hydrophilic coating agent (Col. 3, lines 46-50). The preparation is suitable for administration to ruminants (Col. 4, lines 3-16). Examples of non-hydrophilic covering agents such as hydrogenated vegetable fats and carnauba wax are disclosed (Col. 5, lines 1-17). Feed materials obtained by blending the coated active ingredient preparation with feed raw material and pelletization into feed pellets is disclosed (Col. 6, lines 36-67). Table 1 discloses the active material with a coating where “the compound with “coating” is obtained by coating an ascorbic acid phosphoric ester salt with carnauba wax using a conventional method” (Col. 10, lines 1-4).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a composition of choline chloride for ruminants with choline chloride in the core, coated with hydrophobic materials such as carnauba wax and hydrogenated oils, as suggested by Iijima, combine it with the pelletized feed composition for ruminants comprising choline, as taught by Spires, in view of the use of carnauba wax coating on a cattle feed preparation that undergoes pelletization (involving heating and pressurization), as taught by Ito, and produce the instant invention.

One of ordinary skill in the art would do this because the use of choline in ruminant feed pellets is known in the art, as evidenced by Spires, and Ito teaches that

carnauba wax is used as an outer coating of the ruminant feed preparation core undergoing pelletization (which involves heating and pressurization). One of ordinary skill in the art would have a reasonable expectation of success in producing a functional pelletized ruminant feed material comprising a core of choline chloride coated with hydrogenated vegetable oil, and further coated with carnauba wax.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Regarding instant claim 1, the limitation of a composition of matter for feeding to a ruminant would have been obvious over the ruminant composition, as taught by Iijima (Col. 2, lines 3-9), in view of the feed pellets for ruminants comprising choline, as taught by Spires (Col. 13, lines 10-25 and Col. 14, lines 34-49), and further in view of the cattle feed pellets, as taught by Ito (Col. 6, lines 36-67). The limitation of the composition as a pellet comprising particles compressed together via pelletization would have been obvious over the feed pellets for ruminants comprising choline, as taught by Spires (Col. 13, lines 10-25 and Col. 14, lines 34-49), and further in view of the cattle feed pellets, as taught by Ito (Col. 6, lines 36-67). The limitations of each of the particles containing choline chloride to be administered in a rumen-protected and post-ruminally effective form would have been obvious over the granular composition that is “capable of reaching an abomasum and downstream thereof substantially in the form of granules,

without easily dissolved or decomposed in the rumen", as taught by Iijima (Col. 2, lines 3-9). The limitation of the core mainly consisting of choline chloride in the form of a dry, crystalline powder and, in combination, the protective coating surrounding the core comprises an outer, continuous layer mainly consisting of carnauba wax and an inner, continuous layer consisting of a hydrophobic substance selected from the group consisting of vegetable oils, hydrogenated vegetable oils, stearic acid and mixtures thereof would have been obvious over the choline chloride in the core of the granule (Col. 2, lines 45-46) and hydrogenated palm oil, hydrogenated soybean oil, stearic acid, and carnauba wax as the overcoating agents for the granules, as taught by Iijima (Col. 3, lines 34-40 and lines 50-56) in view of the carnauba wax coating taught by Ito (Col. 10, lines 1-4). The limitation of the inner layer providing effective protection of the choline chloride from moisture would have been obvious over the pelletized feed preparation taught by Ito that undergoes heating or pressurization, as taught by Ito (Col. 2, lines 25-59).

Regarding instant claims 2-4, the limitation of micronized choline chloride would have been obvious over the Iijima teaching of ground choline chloride and particle size of 150μm (Col. 4, lines 18-27). One of ordinary skill in the art would grind the choline chloride and vary the particle size in the composition in order to optimize the rumen protection.

Regarding instant claims 5-6, the limitation of choline chloride percentage in the core would have been obvious over the Iijima teaching of 40% to 70% by weight of choline chloride in the granules (Col. 2, lines 47-52). One of ordinary skill in the art

would vary the amount of choline chloride in the core during routine experimentation, in order to optimize the efficacy of the coated composition. The recited percentages are obvious variants unless there is evidence of criticality or unexpected results.

Regarding instant claims 7 and 39, the limitations of the core comprising additional substance, particularly a flow modifier, would have been obvious over the teaching of Iijima where talc is used in the core composition along with choline chloride (Col. 8, Example 1 Granulation, lines 32-36). Talc is known as a flow modifier in the art.

Regarding instant claims 22-26, the percentages of the additional substances in the core would have been obvious over the teaching of Iijima (Col. 8, Example 1 Granulation, lines 32-36). The percentages are obvious variants unless there is evidence of criticality or unexpected results.

Regarding instant claims 27-28, the percentages of the core weight with respect to the whole particle would have been obvious over the teaching of Iijima (Col. 8, Example 1 Granulation, lines 32-36). One of ordinary skill in the art would vary the percentage of core with respect to the coatings during the process of routine optimization.

Regarding instant claims 29-30, the percentages of the carnauba with respect to the outer layer would have been obvious over the carnauba wax coating taught by Ito (Col. 10, lines 1-4). Since Ito does not disclose other ingredients in this coating, one of ordinary skill in the art would use 100% carnauba wax in the outer layer and would vary

the percentage of carnauba wax with respect to the outer layer during the process of routine optimization.

Regarding instant claims 31-38, the limitations of a rigidity-controlling agent mixed with carnauba wax would have been obvious over the teaching of Iijima. Iijima teaches hydrogenated palm oil, hydrogenated bean oil, hydrogenated coconut oil, stearic acid, carnauba wax etc. as hydrophobic binders (Col. 3, lines 34-40). One of ordinary skill in the art would find it obvious to combine the lower melting hydrogenated vegetable oils with the higher melting carnauba wax in order to control the rigidity of the coating layer. One of ordinary skill in the art would know that the rigidity of the outer coating layer is primarily provided by the higher melting carnauba wax, and by adding a lower melting point component (such as a hydrogenated vegetable oil) would modify the rigidity of the outer coating layer. The percentages of the rigidity-controlling agent would be obvious variants unless there is evidence of criticality or unexpected results.

Regarding instant claims 46-49, the limitations of outer coating percentage and inner coating percentage would have been obvious over the hydrogenated palm oil, hydrogenated soybean oil, stearic acid, and carnauba wax as the overcoating agents for the granules, as taught by Iijima (Col. 3, lines 34-40 and lines 50-56) in view of the carnauba wax coating taught by Ito (Col. 10, lines 1-4).

Regarding instant claim 52, the limitation of the hydrophobic substance would have been obvious over the teaching of hydrogenated palm oil taught by Iijima (Col. 3, line 35).

Regarding instant claims 55-56, the percentage of the protective coating with respect to the whole particle would have been obvious over the overcoating "with a thin film by adding 20 to 40 parts, preferably 20 to 30 parts by weight, of a molten mixture, … of a hydrophobic overcoating agent and a solubility modifier …" as taught by Iijima (Col. 6, line 67 to Col. 7, line 6) and because the percentage of the protective coating would be varied during the process of routine optimization of stabilizing choline chloride in the rumen.

Regarding instant claim 57, the limitation of a feed pellet would have been obvious over the pelleted feed comprising choline, as taught by Spires (Col. 13, lines 10-25) in view of the feed pellets disclosed by Ito (Col. 6, lines 36-67).

Regarding instant claim 58, the limitation of a premix for feed would have been obvious over the premix taught by Spires (Col. 13, lines 10-14) and by the premix taught by Ito (Col. 5, lines 38-43).

Regarding instant claim 59, the limitation of a mash feed in unpelleted form would have been obvious over the composition in the form of pastes and liquid feeds as taught by Spires (Col. 13, lines 20-25).

12. Claims 9-14 **remain** rejected under 35 U.S.C. 103(a) as being unpatentable over Iijima et al. (US 4,948,589) in view of Spires (US 4,394,377) and further in view of Ito et al. (US 6,299,912 B1) and Richardson (US 6,797,291).

The teachings of Iijima, Spires and Ito are stated above.

Iijima, Spires and Ito do not expressly teach silicates as flow modifiers.

Richardson teaches compositions for stabilizing a hygroscopic bioactive substance, such as choline chloride and also providing adequate rumen protection in ruminant feeds (Abstract). The choline chloride is encapsulated "with a lipid coating in an amount sufficient to retain at least about 60 wt % of the hygroscopic ingredient after the encapsulated ingredient is combined with the moist composition for a time period of at least about 1 day; and … combining the encapsulated hygroscopic ingredient with the moist composition" (Col. 3, lines 41-47). The hygroscopic ingredient can be choline chloride (Col. 3, line 48). The moist composition is a ruminant feed (Col. 3, lines 54-55). Hydrogenated vegetable (soybean) oil is the preferred lipid for coating (Col. 3, lines 64-65). Hydrogenated vegetable oil can be mixed with lesser amounts of wax (Col. 3, line 66 to Col. 4, line 5). It is further disclosed that, "skilled practitioners also recognize that flow agents, such as finely-divided silica, can be admixed with the particles of the invention to facilitate handling" (Col. 10, lines 11-13).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a composition of choline chloride for ruminants with choline chloride in the core, coated with hydrophobic materials such as carnauba wax and hydrogenated oils, as suggested by Iijima, combine it with the pelletized feed composition for ruminants comprising choline, as taught by Spires, in view of the use of carnauba wax coating on a cattle feed preparation that undergoes pelletization (involving heating and pressurization), as taught by Ito, and further in view of the use of silica as a flow agent, as taught by Richardson, and produce the instant invention.

One of ordinary skill in the art would do this because Richardson teaches, "skilled practitioners also recognize that flow agents, such as finely-divided silica, can be admixed with the particles of the invention to facilitate handling" (Col. 10, lines 11-13).

Regarding instant claims 9 and 10, the limitations of silicate and aluminosilicate would have been obvious over the sodium aluminosilicate teaching of Richardson (Col. 4, lines 6-11). Richardson teaches "the encapsulates can contain additives whose role is to facilitate the implementation of the techniques for preparing these encapsulates or to improve the physicochemical characteristics … if included, these additives generally represent only a few percent by weight of the coating" (Col. 9, lines 46-62).

Regarding instant claim 11, the flow modifiers including silica would have been obvious over the silica teaching of Richardson (Col. 10, lines 11-13).

Regarding instant claims 12-14, the percentage of flow modifier would have been obvious over the Richardson teaching that "these additives are typically added in the range of 1 to 30 percent by weight" (Col. 9, lines 61-62).

13. Claims 15-18 and 41 **remain** rejected under 35 U.S.C. 103(a) as being unpatentable over Iijima et al. (US 4,948,589) in view of Spires (US 4,394,377) and further in view of Ito et al. (US 6,299,912 B1) and Brommelsiek et al. (US 5,766,668).

The teachings of Iijima, Spires and Ito are stated above.

Iijima, Spires and Ito do not expressly teach stearates as binders acting as moisture barriers in the core composition.

Brommelsiek teaches a choline feed stock precursor having greater than about 80-wt% of choline chloride, a lubricating agent, and an excipient (Abstract). Lubricants such as stearate salts are added to the spray drying system (Col. 7, lines 17-25). "The lubricant may be added during processing in concentrations which range from about 0 to 10 wt-% of the finished product …" (Col. 7, lines 26-27). "The ratio of calcium stearate to choline chloride may range from about 0.01 to 1 to about 0.06 to 1" (Col. 7, lines 46-49).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a composition of choline chloride for ruminants with choline chloride in the core, coated with hydrophobic materials such as carnauba wax and hydrogenated oils, as suggested by Iijima, combine it with the pelletized feed composition for ruminants comprising choline, as taught by Spires, in view of the use of carnauba wax coating on a cattle feed preparation that undergoes pelletization (involving heating and pressurization), as taught by Ito, use of silica as a flow agent, as taught by Richardson, and use lubricants such as stearate salts, as taught by Brommelsiek, and produce the instant invention.

One of ordinary skill in the art would do this because Brommelsiek teaches that inclusion of stearate salts as lubricants is "useful in producing a stable choline product … this constituent assists in providing lubricity to the system during spray-drying and preventing deliquescence of the final composition" (Col. 4, lines 40-45). Since choline chloride is known in the art to be hygroscopic, using stearates to prevent the hygroscopic nature of the coated core of choline chloride would have been obvious to

one of ordinary skill in the art. Even though Brommelsiek teaches spray drying liquid choline chloride, the end result is still a powdered choline chloride and lubricants are added to prevent deliquescence.

Regarding instant claims 15-18 and 41, the limitation of the binder and the percentage of binder acting as a moisture barrier in the core would have been obvious over the teaching of Brommelsiek that 0-10% of lubricant can be used in the composition (Col. 7, lines 26-27). One of ordinary skill in the art would vary the percentage during the process of routine experimentation.

14. Claims 20-21 and 43-45 **remain** rejected under 35 U.S.C. 103(a) as being unpatentable over Iijima et al. (US 4,948,589) in view of Spires (US 4,394,377) and further in view of Ito et al. (US 6,299,912 B1), Richardson (US 6,797,291), and Brommelsiek et al. (US 5,766,668).

The teachings of Iijima, Spires, and Ito are stated above.

Iijima, Spires, and Ito do not expressly teach silicates as flow modifiers or stearates as binders acting as moisture barriers in the core composition.

The teachings of Richardson (with respect to silicates) and Brommelsiek (with respect to stearates as binders) are stated above.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a composition of choline chloride for ruminants with choline chloride in the core, coated with hydrophobic materials such as carnauba wax and hydrogenated oils, as suggested by Iijima, combine it with the pelletized feed

composition for ruminants comprising choline, as taught by Spires, in view of the use of carnauba wax coating on a cattle feed preparation that undergoes pelletization (involving heating and pressurization), as taught by Ito, further use silica as a flow agent, as taught by Richardson, and use lubricants such as stearate salts, as taught by Brommelsiek, and produce the instant invention.

One of ordinary skill in the art would do this because Richardson teaches silica as a flow agent and Brommelsiek teaches lubricants such as stearates to reduce the hygroscopic nature of encapsulated choline chloride which has an impact on ruminant feed storage and stability.

Regarding instant claims 20-21, 43-45, the limitations of percent choline chloride in the core, percent of flow modifier silica, percent of calcium stearate, percent of protective coating (outer and inner layers), and final particle size would have been obvious over the teachings of Iijima (Col. 6, line 67 to Col. 7, line 6), Riga (Col. 33, lines 38-50), Richardson (Col. 10, lines 11-13), and Brommelsiek (Col. 7, lines 26-27). One of ordinary skill in the art would vary the levels of the components and coatings in order to optimize the stability of the choline chloride in the rumen. The percentages and particle sizes recited are obvious variants unless there is evidence of criticality or unexpected results.

Response to Arguments

15. Applicant's arguments, see Pages 11-14, filed 10/20/09, with respect to the rejection of claims under 35 USC § 103(a) have been fully considered but are not persuasive.

Applicant argues that the criticality to the success of the invention was to have two layers, each layer of a particular material; the first layer was a hydrophobic substance selected from the group consisting of vegetable oils, hydrogenated vegetable oils, stearic acid and mixtures thereof; the first layer is to serve the traditional purpose of rumen by-pass, that is, to protect the hygroscopic core material from humidity attack in the rumen; the second layer, mainly consisting of carnauba wax, was needed to effectively protect the first layer and the core from degradation from abrasion, pressure, and mechanical and thermal stress encountered during the pelletization of the particles into an animal feed pellet.

The Examiner acknowledges the points made by Applicants, however, the structure of the composition as recited in instant claims, i.e., a core containing choline chloride and a binder, a layer surrounding the core containing a hydrophobic material (for example an oil), and a second layer surrounding the hydrophobic layer containing carnauba wax, is suggested by the composition with a structure that has a core containing choline chloride granule, and hydrophobic coating substances (such as hydrogenated palm oil, hydrogenated soybean oil, stearic acid) and carnauba wax as the overcoating agents for the granules by Iijima (Col. 2, lines 45-46, Col. 3, lines 34-40 and lines 50-56). The supporting reference, Ito, teaches a carnauba wax outer coating

or covering (Col. 10, lines 1-4). Since the structure of the composition, i.e., the structural components and the arrangement of the structural components (core with choline chloride, hydrophobic coating and carnauba wax over-coating) is taught by the prior art, instant claims are rendered obvious. The combination of Iijima and Ito is proper because Ito teaches that carnauba wax is used as an outer coating of the ruminant feed preparation core undergoing pelletization (which involves heating and pressurization).

Applicant argues that the Spires reference does not add any coating layers prior to pelletization. However, the Spires reference is combined with Iijima and Ito. Iijima and Ito teach carnauba wax as an overcoating and are combined with Spires, which is relied upon for the teaching of pelletized feed composition for ruminants comprising choline.

Applicant argues that Ito is not directly on point, since the core material, L-ascorbic acid-2-phosphoric ester salt, has very low solubility in water, and thus is not a hygroscopic material particularly susceptible to humidity attack in the rumen. Applicant argues that Ito is like all the other conventional or traditional rumen by-pass patents which teach a single layer of hydrophobic substance coating to protect the core from humidity attack in the rumen.

This is not persuasive because Ito is relied upon for the teaching of coating a core with a wax and for the teaching of pelletized feed materials for ruminants. One of ordinary skill in the art would find it obvious to combine the teachings of Iijima, Ito and Spires because they teach ruminant feed compositions and the supporting references (Ito and Spires) teach pelletization of the ruminant feed. One of ordinary skill in the art would use the overcoating with carnauba wax teaching of Iijima with the teachings of Ito

and Spires in order to protect the core from humidity, and from the harsh conditions present during pelletization.

Applicant argues that coating the first layer with a second layer of carnauba wax protects the first layer from degradation during the harsh pelletization process.

However, the claims are directed to a composition. The structure of the composition is rendered obvious by the teachings of Iijima, Spires, and Ito. The claims are not directed to a process of making a pelletized feed, a pelletization process that includes the coated cores, or a process of using the coated cores in pelletization. The harsh pelletization process is a future intended use of the cores and is not given patentable weight.

Applicant argues that they have recognized the problem not recognized previously, that is, the need for a protective second layer to protect the first layer during pelletization, and have also come up with a solution to this problem, that is, providing a second layer mainly consisting of carnauba wax effective to protect the first layer from degradation, from abrasion, pressure and mechanical and thermal stress encountered during pelletization of the particles into an animal feed pellet. Applicant argues that it is clear that the present invention is an important and dramatic advance over the prior art and is accordingly patentable subject matter.

This is not persuasive because something which is old does not become patentable upon the discovery of a new property. Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not

necessarily make the claim patentable. *In re Best,* 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). Please see MPEP 2112.

Moreover, obviousness can be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so. *In re Kahn,* 441 F.3d 977, 986, 78 USPQ2d 1329, 1335 (Fed.Cir. 2006). Please see MPEP 2143. In this case, Iijima teaches the core containing choline chloride, hydrophobic coatings and carnauba wax as an overcoating. Spires and Ito provide the teaching of pelletized ruminant feed compositions comprising choline, and Ito in particular teaches carnauba wax coating. One of ordinary skill in the art would find it obvious that when the composition comprising a carnauba wax overcoating (Iijima and Ito) is subjected to a harsh pelletization process (Spires and Ito), the carnauba wax overcoating will protect the inner core comprising choline.

"[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). Please see MPEP 2113.

Therefore, the rejection of 04/22/09 is maintained.

Conclusion

16. No claims are allowed.

17. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Conclusion

18. No claims are allowed.

19. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aradhana Sasan whose telephone number is (571) 272-9022. The examiner can normally be reached Monday to Thursday from 6:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax, can be reached at 571-272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Aradhana Sasan/
Examiner, Art Unit 1615

/Robert A. Wax/
Supervisory Patent Examiner, Art Unit 1615